OCT 2 6 2011 K112174(1/2)

P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

zimmer

510(k) Summary

Sponsor:	Zimmer, GmbH Sulzer Allee 8 Winterthur, Switzerland CH-8404
Contact Person:	Stephen H. McKelvey Senior Project Manager, Trauma Regulatory Affairs Telephone: (574) 372-4944 Fax: (574) 371-8760
Date:	July 26, 2011
Trade Name:	*NCB*® Periprosthetic Femur Polyaxial Locking Plate System
Common Name:	Locking Plate System
Classification Names and References:	Single/multiple component metallic bone fixation appliances and accessories - 21 CFR § 888.3030
Predicate Device:	*NCB* Periprosthetic Femur Polyaxial Locking Plate System
Device Description:	The *NCB* Periprosthetic Femur Plate Provisional Instruments are surgically invasive, non-sterile, re-usable devices used to determine the suitable implant length during intra-operative planning as part of the implantation of the *NCB* Periprosthetic Femur Plates.
Intended Use:	The *NCB* Periprosthetic Femur Polyaxial Locking Plate System is indicated for temporary internal fixation and stabilization of fractures and osteotomies of long bones, including: • Periprosthetic fractures • Comminuted fractures • Supracondylar fractures • Fractures in Osteopenic bone • Nonunions • Malunions

Comparison to Predicate Device:

The modified *NCB* Periprosthetic Femur Polyaxial Locking Plate System contains the same implants and instruments as the original *NCB* Periprosthetic Femur Polyaxial Locking Plate System, except for the addition of new optional provisional instruments.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

A bending test was performed to assess the behavior of the Provisionals under high handling force. The acceptance criteria were successfully met.

Radiolucency and the physico-chemical stability of the polyphenylsulfone with barium sulfate material was compared before and after cleaning and sterilization cycles - results showed no discernable or significant differences between pre- and post-processing. There was no evidence of surface changes, etch degradation, material deformation, significant dimensional changes and/or cracking of the provisional materials. The acceptance criteria were successfully met.

Cytotoxicity of the polyphenylsulfone material with barium sulfate was evaluated post-processing. No leachable substances were released in cytotoxic concentrations from the test item. The acceptance criteria were met. In addition, this material has been used in prior orthopedic instrumentation with the same ISO 10993-1 classification and has a long successful history of clinical use.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 2 6 2011

Zimmer, Inc.
% Mr. Stephen McKelvey
Senior Project Manager, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K112174
Trade/Device Name: NCB® Periprosthetic Femur Polyaxial Locking Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: October 3, 2011
Received: October 4, 2011

Dear Mr. McKelvey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112174

Indications for Use

510(k) Number (if known):

Device Name:

NCB® Periprosthetic Femur Polyaxial Locking Plate System

Indications for Use:

The *NCB* Periprosthetic Femur Polyaxial Locking Plate System is indicated for temporary internal fixation and stabilization of fractures and osteotomies of long bones, including:

- Periprosthetic fractures
- Comminuted fractures
- Supracondylar fractures
- Fractures in osteopenic bone
- Nonunions
- Malunions

Prescription Use X AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

10/26/11

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112174